

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

04-10027 JLT

BRUNO HOFMANN, Individually And
On Behalf of All Others Similarly Situated,

Plaintiff,

vs.

PHILIP LAUGHLIN, MICHAEL
SABOLINSKI, ALBERT ERANI, DONNA
ABELLI LOPOLITO, JOHN J. ARCARI,
HERBERT M. STEIN, ALAN ADES,
BERNARD A. MARDEN, ALAN W. TUCK,
NOVARTIS PHARMA AG and
PRICEWATERHOUSECOOPERS LLP,

Defendants.

CIVIL ACTION NO. _____

CLASS ACTION COMPLAINT
FOR VIOLATIONS OF
FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

MAGISTRATE JUDGE DeW

AMOUNT \$ 150 52,364
SUMMONS ISSUED YES
LOCAL RULE 4.1 1
WAIVER FORM 1
MCF ISSUED 1
EMERGENCY 1
1-7-04 EDM

Plaintiff has alleged the following based upon the investigation of plaintiff's counsel, which included a review of SEC filings by Organogenesis, as well as regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company, and plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

INTRODUCTION & OVERVIEW

1. This is a federal class action on behalf of purchasers of the securities of Organogenesis, Inc. ("Organogenesis" or the "Company") between November 15, 1999 and January 30, 2002, inclusive (the "Class Period"), seeking to pursue remedies under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Throughout the Class Period, Organogenesis was a Company with only one commercially available product -- Apligraf, a skin replacement therapy used for severe skin wounds. Thus, while Organogenesis has acquired other technologies, virtually all of the Company's revenues were at all times generated from the sale of Apligraf. Apligraf is described by Organogenesis as having a structure similar to human skin and is described as a "skin construct." The product's human skin-like properties allow this product to be used by doctors to aid in the healing of certain types of skin ulcers, and other epidermal injuries.

3. At all times throughout the Class Period, defendants were well aware that the Company's business model was entirely dependent upon their ability to mass-produce Apligraf and market it to physicians as an "off-the-shelf," cost-effective product that doctors could use on patients absent hospitalization. Thus, while the Company encountered some difficulties in manufacturing and marketing Apligraf during the first half of 1999, by the inception of the Class Period, defendants assured investors:

(a) that Organogenesis maintained the expertise and ability to manufacture sufficient quantities of Apligraf so that it was foreseeable that the Company could achieve economies of scale and achieve profitability through the sales of only this product;

(b) that the Company maintained marketing agreements with partners such as Novartis, which would allow Organogenesis to obtain the marketing support necessary to sell sufficient quantities of Apligraf, while at the same time retaining enough of the revenue split in these deals to fund operations and achieve profitability; and

(c) that between the Company's marketing agreements with Novartis and others, and through other foreseeable sources of available debt and equity, Organogenesis could foreseeably achieve profitability and sufficiency.

4. Thus, by the inception of the Class Period, while it was fully disclosed that the Company would need to raise additional funding at some point in the future to increase production and distribution, throughout this time, defendants consistently reported that Organogenesis had the necessary funding in place to allow it to achieve the Company's stated, foreseeable near-term objectives. In fact, according to the Company's 1999 Form 10-K filed with the SEC on or about 3/29/00, Organogenesis stated that, *future capital comprised of product sales, research and development support payments and debt and equity financing will be sufficient to fund future operations.*

5. Thus, throughout the Class Period, plaintiff and other members of the Class were led to believe that Organogenesis was able to manufacture Apligraf in sufficient quantities and that other sources of funding were available such that the Company would be able to achieve profitability in the foreseeable near-term. Defendants consistently reported that Organogenesis' results were "*consistent with the transition in progress from a research focused company to a research based operating company with a novel medical product in introduction phase,*" and that the Company had necessary and available funding sources, from foreseeable sales of debt and equity to both private and public investors which would allow the Company to achieve defendants' plan for sufficiency. Central to this plan, also was a key agreement with Novartis, Organogenesis' Apligraf marketing partner, which purportedly allowed defendants to access *at least \$20 million* through the exercise of a "put" option. This agreement purportedly would allow defendants to raise this money at any time, and thereby maintain a large mega-million "safety net" for the Company.

6. The purported ability of the Company to be able to sell stock to Novartis was also a critical part of Organogenesis' financing plans, because it should have allowed defendants to

raise sufficient funds as needed -- including a purported \$20 million equity put option -- in addition to any other necessary sources of debt or equity financing available to the Company. Again, this financing was also very important to investors, because it provided a purported “safety net” for Organogenesis -- a reserve of cash which defendants could allegedly access as a last resort. The Novartis put agreement was, therefore, during the Class Period, a critical part of defendants’ announced plan to achieve profitability and to avoid bankruptcy.

7. At all times during the Class Period, therefore, Organogenesis represented that it was able to make Apligraf commercially available in a cost effective manner which, even if the Company was forced to incur losses at the early stages of development, would allow Organogenesis to ramp up production and soon be able to fund operations from sales. Defendants consistently represented both prior to and during the Class Period, the Company was sufficiently well funded to carry out defendants’ business plan.

8. Unbeknownst to investors, however, throughout the Class Period, the Company was suffering from a host of undisclosed adverse factors which were negatively impacting its business and which would cause it to report declining financial results, materially less than the market expectations defendants had caused and cultivated. In particular:

- At all times during the Class Period, it was not true that defendants could achieve profitability through the sale of Apligraf under the terms, or even the revised terms, of the Novartis marketing agreement, which did not provide Organogenesis with enough of the revenues or profits provided through such Apligraf sales to offset the extremely high cost of production or to offset other undisclosed manufacturing problems such as defective products and recalls.
- Throughout the Class Period, undisclosed problems related to the manufacture and marketing of Apligraf was leading to even higher costs and further reducing profitability. Manufacturing problems and delays were retarding production scale and marketing issues were reducing sales. As investors would only learn following the Class Period, the Company’s own sales force was encountering resistance throughout that time concerning the cost and complexity of its products and the actual and/or perceived difficulties in physician reimbursement for Apligraf.

- Throughout the Class Period, Organogenesis was underfunded and there was no reasonable basis to report that the Company could foreseeably fund operations throughout the Class Period, based on available sources of loans, debt and/or equity sales. Moreover, as defendants were well aware but failed to disclose, it was not true that the Company could force Novartis to provide the full complement of its funding as defendants consistently represented, as certain undisclosed conditions existed. Organogenesis could not meet conditions precedent to Novartis' requirement to provide at least \$10 million of its purported commitment to Organogenesis. It was not true that other sources of funding remained available to defendants so as to preserve corporate viability.
- Throughout the Class Period, defendants failed to disclose that high management turn-over at the Company was having and would continue to have a disruptive effect on the operations and oversight of Organogenesis, such that it was also not foreseeable at any time during the Class Period that Organogenesis would be able to achieve profitability in the near-term or to attain guidance sponsored and/or endorsed by defendants.
- As a result of the aforementioned adverse conditions which defendants failed to disclose, throughout the Class Period, defendants lacked any reasonable basis to claim that Organogenesis was operating according to plan, that sufficient sources of funding were achieved and/or available to Organogenesis or that the Company could maintain profitability or even remain a viable entity in the foreseeable near-term.

9. Defendants were motivated to and did conceal the true operational and financial condition of Organogenesis, and materially misrepresented and failed to disclose the conditions that were adversely affecting Organogenesis throughout the Class Period, because it enabled insiders, including certain defendants, to sell over 6.2 million shares of Company stock and/or securities valued at over \$68.8 million, prior to any proper disclosure to the market.

10. Defendants' scheme also, ultimately, allowed Erani and Ades and their family members to improperly acquire the remaining assets of Organogenesis through a leveraged buyout through bankruptcy proceedings -- after defendants' actions drove the Company into bankruptcy and after they sufficiently interfered with these proceedings so as to guarantee that Erani and Ades and their family members acquired total domination and control over what was left of Organogenesis. Thus, through their illegal and improper actions which ultimately forced the Company into Chapter 11, defendants not only were able to wipe out the equity interest of all

of the Company's outside shareholders, but they were also able to renegotiate their agreement with Novartis -- *which as defendants knew or recklessly disregarded throughout the Class Period, was causing the Company to lose money on every unit sale of Apligraf!*

JURISDICTION AND VENUE

11. The claims asserted herein arise under and pursuant to Sections 10(b) and 20(a) of the Exchange Act [15 U.S.C. §§ 78j(b) and 78t(a)] and Rule 10b-5 promulgated thereunder by the United States Securities and Exchange Commission ("SEC") [17 C.F.R. § 240.10b-5].

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act [15 U.S.C. § 78aa].

13. Venue is proper in this District pursuant to Section 27 of the Exchange Act, and 28 U.S.C. § 1391(b). Organogenesis maintains its principal place of business in this District and many of the acts and practices complained of herein occurred in substantial part in this District.

14. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications and the facilities of the national securities markets.

PARTIES

15. Plaintiff Bruno Hofmann, as set forth in the accompanying certification, incorporated by reference herein, purchased the common stock of Organogenesis at artificially inflated prices during the Class Period and has been damaged thereby.

16. Non-party Organogenesis is a Delaware corporation with its principal place of business at 150 Dan Road, Canton, MA 02021. Organogenesis designs, manufactures and sells medical products containing living cells and/or natural connective tissue, including living tissue

replacements, cell-based organ asset devices and other tissue-engineered products. The Company's lead product, Apligraf living skin construct, is promoted as being the only product containing living human cells to gain FDA marketing approval in the United States.

17. Defendant **NOVARTIS PHARMA AG** ("Novartis") is a Swiss based pharmaceutical and drug company, which throughout the Class Period was the purported marketing partner of the Company and a principal shareholder in Organogenesis, holding as many as 2.88 million shares, or more than 6% of the Company's shares issued and outstanding during that time. As a result of the Company's bankruptcy filing and the transcripts related thereto, investors have now learned that Novartis worked with Organogenesis to artificially inflate sales forecasts, as well as failing to issue any corrective statements concerning its commitment to provide funding to the Company, which commitment defendants materially mischaracterized throughout the Class Period.

18. Defendant **PRICEWATERHOUSECOOPERS LLP** ("PricewaterhouseCoopers") was, throughout the Class Period, the purported independent auditors of the Company. During this time PricewaterhouseCoopers provided year-end reports which certified the Company's financial statements and its cash position, and consistently failed to alert investors to the fact that, at no time during the Class Period, did the Company have the ability to fund operations through product sales, or that Organogenesis was actually losing money on each sale of Apligraf. It was only after the end of the Class Period, after the Company had finally disclosed that it was impossible to fund operations with product sales that PricewaterhouseCoopers finally, belatedly, issued a "going concern opinion" on the Company -- an opinion which should have been in place since the inception of the Class Period.

19. Defendant **PHILIP LAUGHLIN** (“Laughlin”) was during the relevant period, President and a Director and member of the Company’s Executive Committee of Organogenesis. Defendant Laughlin assumed these positions immediately prior to the inception of the Class Period, on or about, October 5, 1999 and later, on or about, January 1, 2001 also assumed the role of Chief Executive Officer. Defendant Laughlin retained these positions of power and control over the Company until his sudden and unexpected departure announced on or about May 16, 2001. During the Class Period, defendant Laughlin signed the Company’s SEC filings, including, but not limited to, Organogenesis’ Form(s) 10-K and/or the materially false and misleading Registration Statements and joint Proxy/Prospectus issued in connection with the sale and offering of stock by the Company and certain “Selling Shareholders” (as defined herein *infra*).

20. Defendant **MICHAEL SABOLINSKI** (“Sabolinski”) was during the Class Period, President, Chief Executive Officer and a member of the Board of the Company, having assumed those positions on or about May 16, 2001, upon the resignation of defendant Laughlin. Prior to assuming the aforementioned positions and also during the Class Period, defendant Sabolinski also served as the Company’s Senior Vice President Medical and Regulatory Affairs. Defendant Sabolinski abandoned his position at the Company on or about April 5, 2002, after less than one year after assuming the leadership of Organogenesis. During the Class Period, defendant Sabolinski signed the Company’s SEC filings, including, but not limited to, Organogenesis’ Form(s) 10-K and/or the materially false and misleading Registration Statements and joint Proxy/Prospectus issued in connection with the sale and offering of stock by the Company and certain “Selling Shareholders” (as defined herein *infra*).

21. Defendant **ALBERT ERANI** (“Erani”) was during the relevant period, a member of the Board of the Company and on or about January 1, 2000 assumed the role of Chairman of the Board of Organogenesis. Defendant Erani served as Chairman of the Board of the Company until his sudden and unexpected departure on or about January 4, 2002. During the Class Period, defendant Erani signed the Company’s SEC filings, including, but not limited to, Organogenesis’ Form(s) 10-K and/or the materially false and misleading Registration Statements and joint Proxy/Prospectus issued in connection with the sale and offering of stock by the Company and certain “Selling Shareholders” (as defined herein *infra*).

22. Defendant **ALAN ADES** (“Ades”) was nominated and appointed Chairman, President and Chief Executive Officer of the Company following the end of the Class Period on or about October 2002. Defendant Ades is the cousin of defendant Erani, and was also a member of the group of investors who took the Company private through a leveraged acquisition in bankruptcy. Defendant Ades was an active participant in the fraud alleged herein. It has been reported that defendant Ades, with the aid and complicity of other defendants named herein, acted to assure that other interested parties were not able to successfully participate in the ultimate sale of the Company and that defendant Ades, with the aid and complicity of other insiders, was then able to acquire the Company for a lower price, further depriving investors of a return on their investment in Organogenesis.

23. Defendant **DONNA ABELLI LOPOLITO** (“Lopolito”) was during the relevant period, Chief Financial Officer and Vice President - Finance and Administration of Organogenesis. During the Class Period, defendant Lopolito signed the Company’s SEC filings, including, but not limited to, Organogenesis’ Form(s) 10-K and/or the materially false and misleading Registration Statements and joint Proxy/Prospectus issued in connection with the sale

and offering of stock by the Company and certain "Selling Shareholders" (as defined herein *infra*).

24. Defendant **JOHN J. ARCARI** ("Arcari") was during the relevant period, Chief Financial Officer and Vice President - Finance and Administration of Organogenesis, having replaced defendant Lopolito on or about April 30, 2000. Defendant Arcari served in the aforementioned positions until his sudden and unexpected departure on or about May 14, 2002. During the Class Period, defendant Arcari signed the Company's SEC filings, including, but not limited to, Organogenesis' Form(s) 10-K and/or the materially false and misleading Registration Statements and joint Proxy/Prospectus issued in connection with the sale and offering of stock by the Company and certain "Selling Shareholders" (as defined herein *infra*).

25. Defendant **HERBERT M. STEIN** ("Stein") was at the inception of the Class Period, Chairman of the Board and Chief Executive Officer, until his resignation on or about January 1, 2000. Upon his retirement from the aforementioned positions, defendant Stein remained at the Company as a member of the Board and Chairman Emeritus. During the Class Period defendant Stein made materially false and misleading statements about the Company and/or failed to disclose material information necessary to make such statements not false. During the Class Period, defendant Stein also signed the Company's SEC filings, including, but not limited to, Organogenesis' Form(s) 10-K and/or the materially false and misleading Registration Statements and joint Proxy/Prospectus issued in connection with the sale and offering of stock by the Company and certain "Selling Shareholders" (as defined herein *infra*).

26. Defendant **ALAN W. TUCK** ("Tuck") was during the Class Period, Chief Strategic Officer of the Company. During the Class Period, defendant Tuck also made materially false and misleading statements and/or signed the Company's SEC filings, including,

but not limited to, Organogenesis' Form(s) 10-K and/or the materially false and misleading Registration Statements and joint Proxy/Prospectus issued in connection with the sale and offering of stock by the Company and certain "Selling Shareholders" (as defined herein *infra*).

27. Defendant **BERNARD A. MARDEN** ("Marden") was, during the Class Period, a director of the Company and one of its private investors. During the Class Period, defendant Marden also made materially false and misleading statements and/or signed the Company's SEC filings, including, but not limited to, Organogenesis' Form(s) 10-K and/or the materially false and misleading Registration Statements and joint Proxy/Prospectus issued in connection with the sale and offering of stock by the Company and certain "Selling Shareholders" (as defined herein *infra*).

28. The defendants referenced above in ¶¶ 19 - 27 are referred to herein as the "Individual Defendants."

29. Because of the Individual Defendants' positions with the Company, or relations with Company insiders, they had access to the adverse undisclosed information about its business, operations, products, operational trends, financial statements, markets and present and future business prospects via access to internal corporate documents (including the Company's operating plans, budgets and forecasts and reports of actual operations compared thereto), conversations and connections with other corporate officers and employees, attendance at management and Board of Directors meetings and committees thereof and via reports and other information provided to them in connection therewith and/or otherwise actively participated in the fraudulent scheme alleged herein.

30. It is appropriate to treat the Individual Defendants as a group for pleading purposes and to presume that the false, misleading and incomplete information conveyed in the

Company's public filings, press releases and other publications as alleged herein are the collective actions of the narrowly defined group of defendants identified above. Each of the defendants, by virtue of their high-level positions with the Company and/or relations with company insiders, directly participated in the management of the Company, was directly involved in the day-to-day operations of the Company at the highest levels and was privy to confidential proprietary information concerning the Company and its business, operations, products, growth, financial statements, and financial condition, as alleged herein and/or otherwise actively participated in the fraudulent scheme alleged herein. Said defendants were involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein, were aware, or recklessly disregarded, that the false and misleading statements were being issued regarding the Company, and approved or ratified these statements, in violation of the federal securities laws.

31. As officers and controlling persons of a publicly-held company whose common stock was, and is, registered with the SEC pursuant to the Exchange Act, and was traded on the American Stock Exchange (the "AMEX"), and governed by the provisions of the federal securities laws, the Individual Defendants each had a duty to disseminate promptly, accurate and truthful information with respect to the Company's financial condition and performance, growth, operations, financial statements, business, products, markets, management, earnings and present and future business prospects, and to correct any previously-issued statements that had become materially misleading or untrue, so that the market price of the Company's publicly-traded securities would be based upon truthful and accurate information. The Individual Defendants' misrepresentations and omissions during the Class Period violated these specific requirements and obligations.

32. The Individual Defendants participated in the drafting, preparation, and/or approval of the various public and shareholder and investor reports and other communications complained of herein and were aware of, or recklessly disregarded, the misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature and/or otherwise actively participated in the fraudulent scheme alleged herein. Because of their Board membership and/or executive and managerial positions with Organogenesis, each of the Individual Defendants had access to the adverse undisclosed information about Organogenesis' business prospects and financial condition and performance as particularized herein and knew (or recklessly disregarded) that these adverse facts rendered the positive representations made by or about Organogenesis and its business issued or adopted by the Company materially false and misleading and/or otherwise actively participated in the fraudulent scheme alleged herein.

33. The Individual Defendants, because of their positions of control and authority as officers and/or directors of the Company, or relations with officers and/or directors, were able to and did control the content of the various SEC filings, press releases and other public statements pertaining to the Company during the Class Period. Each Individual Defendant was provided with copies of the documents alleged herein to be misleading prior to or shortly after their issuance and/or had the ability and/or opportunity to prevent their issuance or cause them to be corrected. Accordingly, each of the Individual Defendants is responsible for the accuracy of the public reports and releases detailed herein and is therefore primarily liable for the representations contained therein and/or otherwise actively participated in the fraudulent scheme alleged herein.

34. Each of the defendants is liable as a participant in a fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Organogenesis common stock by disseminating materially false and misleading statements and/or concealing material adverse

facts. The scheme: (i) deceived the investing public regarding Organogenesis' business, operations, management and the intrinsic value of Organogenesis common stock; (ii) enabled the defendants and Company insiders to sell over \$68.8 million worth of Company stock to investors during the Class Period. Of this amount, defendants sold over 5.78 million shares of the Company's securities in a series of public stock offerings, private equity offerings and other debt and/or equity sales of Organogenesis stock for proceeds of over \$68.3 million; and (iii) caused plaintiff and other members of the Class to purchase Organogenesis securities at artificially inflated prices.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

35. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the securities of Organogenesis between November 15, 1999 and January 30, 2002 inclusive (the "Class") and who were damaged thereby. Excluded from the Class are defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which defendants have or had a controlling interest.

36. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Organogenesis common shares were actively traded on the AMEX. As of November 2, 2001, the Company had over 37.0 million shares issued and outstanding. While the exact number of Class members is unknown to plaintiff at this time and can only be ascertained through appropriate discovery, plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Organogenesis or its transfer agent and may be

notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

37. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by defendants' wrongful conduct in violation of federal law that is complained of herein.

38. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

39. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by defendants' acts as alleged herein;

(b) whether statements made by defendants to the investing public during the Class Period misrepresented material facts about the business, operations and management of Organogenesis; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

40. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

SUBSTANTIVE ALLEGATIONS

Background

41. **The Company.** Organogenesis was organized as a Delaware corporation in 1985, and its principal offices are located at 150 Dan Road, Canton, Massachusetts 01021. Organogenesis describes itself as a “tissue engineering firm” that designs, develops and manufactures medical products containing living cells and/or natural connective tissue. For Organogenesis, tissue engineering involves developing and manufacturing medical products containing actual living human cells.

42. **Operations.** Prior to the inception of the Class Period, Organogenesis appeared to be a Company with a very unique product, but a Company which was research-centric and which had little product manufacturing experience. Complicating matters, the Company’s main product, Apligraf a “tissue replacement” therapy, discussed in more detail below, was difficult to manufacture and required very specialized manufacturing procedures and techniques. As evidence of the difficulties associated with Apligraf production surfaced during mid-1998, the Company was forced to recall several lots of Apligraf -- accounting for more than 10% of monthly production at that time -- for contamination reasons.

43. In addition to manufacturing issues, the marketing of Apligraf was also difficult because, until early in the Class Period, Apligraf had *not* been approved for Medicare or Medicaid reimbursement -- leaving doctors with a vast array of red tape to get reimbursed for the product. The manufacture and marketing of Apligraf proved so difficult that in the year prior to the inception of the Class Period, sales of Apligraf were well below expectations. In fact, when the Company reported fiscal year 1998 results in March of 1999, Organogenesis reported Apligraf sales of only \$335,000 -- well below product sales of \$1.3 million that defendants had

guided the market to expect. The result of these lower than expected sales was larger losses, and by the end of 4Q:98 the Company posted a loss of \$0.19 per share.

44. Moreover, as a result of these difficulties, during 1999, defendants reported less than consistent sales of Apligraf, but the trend overall, bolstered by defendants' guidance, appeared bullish. While sales in July 1999 dipped 11% below June sales, combined sales during those two months of over 1200 Apligraf units appeared to confirm defendants' representations that the Company was heading towards profitability. These increased sales, however, still left Organogenesis behind defendants' oft-repeated goal of being operationally profitable by 4Q:99, which would require sales of approximately 8,000 units per month at that time.

45. The manufacturing and marketing problems which limited the sale of Apligraf also raised issues concerning the funding of the Company and its ability to remain in operations long enough to achieve profitability. In this regard, while the Company initially had issued very aggressive predictions, forecasting operational break-even by 4Q:99 and full funding by that time, by the inception of the Class Period, defendants had already revised these expectations and had taken a longer-term view towards profitability. By the inception of the Class Period, and at all times thereafter, however, defendants consistently reported that sufficient sources of funding were available and that Organogenesis received or would receive sufficient profits from sales of Apligraf that the Company still expected to achieve profitability in the foreseeable near-term.

46. **Funding Representations.** Thus, by the inception of the Class Period, while it was fully disclosed that the Company would need to raise additional funding at some point in the future to increase production and distribution, by this time and consistently thereafter, defendants reported that Organogenesis had the necessary funding in place to allow it to achieve the Company's stated, foreseeable near-term objectives. In fact, according to the Company's 1999

Form 10-K, filed with the SEC on or about March 29, 2000, Organogenesis stated that, “future capital comprised of product sales, research and development support payments and debt and equity financings will be sufficient to fund future operations into 2001,” and additional sources could be relied on to fund operations thereafter.

47. Moreover, according to statements made by defendants and filed with the SEC, while there could be “no assurance” that additional funding might not be required, Organogenesis’ funding was already in place and sufficient. According to defendants, by the inception of the Class Period, the Company was sufficiently funded barring only unforeseen circumstances, unplanned contingencies, “delays,” or unexpected “changes,” such as the following:

- Delays in obtaining regulatory approvals of products, and timing of product launches;
- Delays in commercial acceptance and reimbursement when product launches occur;
- Changes in the progress of research and development programs; and
- Changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies.

48. Thus, throughout the Class Period, defendants led investors to believe that Organogenesis was able to manufacture Apligraf in sufficient quantities and that other sources of funding were available such that the Company would be able to achieve profitability in the foreseeable near-term. Defendants consistently reported that the Company had necessary and available funding sources, from foreseeable sales of debt and equity to both private and public investors which would allow Organogenesis to achieve defendants’ plan for sufficiency. Central to this plan, was a key agreement with Novartis, Organogenesis’ Apligraf marketing partner, which purportedly allowed defendants to access *at least \$20 million* through the exercise of a

“put” option. This agreement purportedly would allow defendants to raise this money at any time, and thereby maintain a mega-million dollar “safety net” for the Company.

49. **Apligraf.** As stated above, throughout the Class Period, Apligraf was the Company’s only commercially available product. While Organogenesis has acquired other technologies, most if not all of the Company’s revenues were at all times generated from the sale of Apligraf. Apligraf has a structure similar to human skin and is described as a “skin construct.” The product’s human skin-like properties allow this product to be used by doctors to aid in the healing of certain types of skin ulcers, and other epidermal injuries.¹ At all times throughout the Class Period, defendants were well aware that the Company’s business model was entirely dependent upon its ability to mass-produce Apligraf and market it to physicians as an “off-the-shelf,” cost-effective product that doctors could use on patients absent hospitalization.

50. By the inception of the Class Period, Apligraf was approved by the FDA for marketing in the United States for the treatment of venous leg ulcers and was pending approval for diabetic leg ulcers. At that time and during the Class Period, Apligraf was a registered trademark of Novartis, the Company’s Apligraf marketing partner. At all times during the Class Period, this marketing agreement with Novartis was consistently touted by defendants as a key to the Company’s profitability. According to defendants’ consistent representations, the marketing agreement with Novartis (both prior to and following the time of its revision) provided Organogenesis with enough of the revenue split generated through Apligraf sales to allow the

¹ According to Organogenesis, Apligraf has an organized, two-layered structure, much like skin, and features the key components of skin - the lower dermal cells (fibroblasts), the upper epidermal cells (keratinocytes) and its key structural protein (collagen). Unlike human skin, however, Apligraf does not contain structures such as blood vessels, hair follicles and sweat glands or other cell types.

Company to grow operations and achieve profitable growth in the foreseeable near-term. Thus, by the inception of the Class Period, defendants represented that Apligraf sales were sufficient. That impression was substantially reinforced when the Novartis agreement was allegedly amended during the Class Period to provide even more revenues to the Company.

51. In addition to simply marketing Apligraf, Novartis was also a significant owner of Organogenesis shares, and during the Class Period owned as many as 2.8 million Company shares -- or over 6% of Organogenesis shares issued and outstanding. Novartis had acquired its shares in the Company through several private equity investments, as well as through certain funding agreements which purportedly allowed Organogenesis to sell stock to Novartis at prices predetermined and at the election of the Company.

52. The purported ability of the Company to be able to sell stock to Novartis was also purportedly a critical part of Organogenesis' financing, because it should have allowed defendants to raise money whenever necessary, up to \$20 million in additional equity financing to any other necessary sources of debt or equity financing available to the Company. Again, this financing was also very important to investors, because it provided a purported "safety net" for Organogenesis -- a reserve of cash which defendants could allegedly access as a last resort. The Novartis put agreement was, therefore, during the Class Period, a critical part of defendants' announced plan to achieve profitability and to avoid bankruptcy,

53. At all times during the Class Period, therefore, Organogenesis represented that it was able to make Apligraf commercially available in a cost-effective manner which, even if the Company was forced to incur losses at the early stages of development, would allow Organogenesis to ramp up production and soon be able to fund operations from sales.

Defendants consistently represented both prior to and during the Class Period, the Company was sufficiently well funded to carry out defendants' business plan.

54. Unbeknownst to investors, however, throughout the Class Period, the Company was suffering from a host of undisclosed adverse factors which were negatively impacting its business and which would cause it to report declining financial results, materially less than the market expectations defendants had caused and cultivated. In particular:

- At all times during the Class Period, it was not true that defendants could achieve profitability through the sale of Apligraf under the terms, or even the revised terms, of the Novartis marketing agreement, which did not provide Organogenesis with enough of the revenues or profits provided through such Apligraf sales to offset the extremely high cost of production or to offset other undisclosed manufacturing problems such as defective products and recalls.
- Throughout the Class Period, undisclosed problems related to the manufacture and marketing of Apligraf was leading to even higher costs and further reducing profitability. Manufacturing problems and delays were retarding production scale, and marketing issues were reducing sales. As investors would only learn following the Class Period, the Company's own sales force was encountering resistance throughout that time concerning the cost and complexity of its products and the actual and/or perceived difficulties in physician reimbursement for Apligraf.
- Throughout the Class Period, Organogenesis was underfunded and there was no reasonable basis to report that the Company could foreseeably fund operations throughout the Class Period, based on available sources of loans, debt and/or equity sales. Moreover, as defendants were well aware but failed to disclose, it was not true that the Company could force Novartis to provide the full complement of its funding as defendants consistently represented, as certain undisclosed conditions existed. Organogenesis could not meet conditions precedent to Novartis' requirement to provide at least \$10 million of its purported commitment to the Organogenesis. It was not true that other sources of funding remained available to defendants so as to preserve corporate viability.
- Throughout the Class Period, defendants failed to disclose that the high management turn-over at the Company was having and would continue to have a disruptive effect on the operations and oversight of Organogenesis, such that it was also not foreseeable at any time during the Class Period that Organogenesis would be able to achieve profitability in the near-term or to attain guidance sponsored and/or endorsed by defendants.
- As a result of the aforementioned adverse conditions which defendants failed to disclose, throughout the Class Period, defendants lacked any reasonable basis to claim

that Organogenesis was operating according to plan, that sufficient sources of funding were achieved and/or available to Organogenesis or that the Company could maintain profitability or even remain a viable entity in the foreseeable near-term.

55. Defendants were motivated to and did conceal the true operational and financial condition of Organogenesis, and materially misrepresented and failed to disclose the adverse conditions that were adversely affecting Organogenesis throughout the Class Period, because it enabled defendants and Company insiders to sell over 6.2 million shares of Company stock and/or securities valued at over \$68.8 million, prior to any disclosure to the market.

**Defendants' Materially False and Misleading
Statements Made During the Class Period**

56. **"Puzzle" Nears Completion.** The Class Period begins on November 15, 1999. On that day, Organogenesis published a release on *Business Wire* announcing financial results for the third quarter of 1999, the period ending September 30, 1999. For 3Q:99 Organogenesis reported total revenues of \$946,000, equal to a net loss of \$0.21 per share, compared to a net loss of \$0.25 per share the prior quarter. According to the release, total expenses for 3Q:99 were \$7.426 million, including one-time technology acquisition charges of \$900,000, compared to a sequential loss of \$8.527 million. This release also quoted defendant Stein, as follows:

Apligraf is a revolutionary technology development to provide significant advantages in wound healing. Alpigraf is FDA approved, well-received by physicians and can be a highly cost-effective therapy for many patients. *The key remaining piece of the puzzle is gaining broad, standardized reimbursement....*

A subsequent release, dated 12/2/99, reported that Apligraf sales reached 755 units in 11/99.

57. Following the publication of the Company's earnings announcement, the price of Organogenesis rallied -- trading from a low of \$6.81 per share on November 15, 1999, to above \$12.30 per share on December 2, 1999.